

AMENDMENTS TO THE CLAIMS:

Claim 1 (Currently Amended): A pharmaceutical composition comprising a bilayer tablet which comprises:

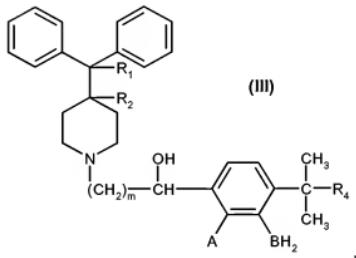
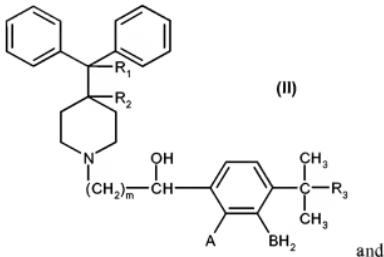
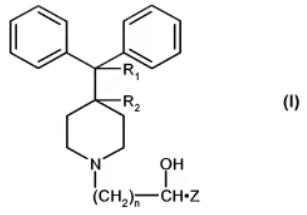
(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) a filler; (ii) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [[2]] 10 wt. % to about [[50]] 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof; and (v) a lubricant; and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' a sugar; (ii)' a disintegrant; and (iii)' a lubricant.

Claim 2 (Original): The composition according to Claim 1, wherein the sympathomimetic drug is selected from the group consisting of pseudoephedrine, phenylephrine, phenylpropanolamine and pharmaceutically acceptable salts thereof.

Claim 3 (Original): The composition according to Claim 2, wherein the sympathomimetic drug is pseudoephedrine hydrochloride.

Claim 4 (Original): The pharmaceutical composition according to Claim 1, wherein the piperidinoalkanol compound has a formula selected from the group consisting of Formulae (I), (II) and (III), as follows:



wherein

R₁ is hydrogen or hydroxy;

R₂ is hydrogen or

R₁ and R₂, taken together, form a second bond between the carbon atoms bearing R₁ and R₂;

R₃ is -CH₃, or -CH₂OH, each A and B is hydrogen or hydroxy, with the provisos that at least one of A or B is hydrogen and one of A or B is other than hydrogen when R₃ is -CH₃ and pharmaceutically acceptable salts and individual optical isomers thereof;

R₄ is -COOH or -COO alkyl, wherein the alkyl moiety has from 1-6 carbon atoms and is straight or branched, each of A and B is hydrogen or hydroxy, with the proviso that at least one of A or B is hydrogen; and pharmaceutically acceptable salts and individual optical isomers thereof;

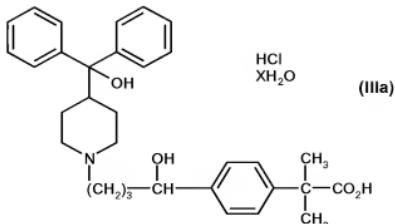
Z is thienyl, phenyl or substituted phenyl wherein the substituents on the substituted phenyl may be attached at the ortho, meta or para positions of the unsubstituted phenyl ring and are selected from the group consisting of a halogen, a straight or branched alkyl moiety having 1-4 carbon atoms, an alkoxy moiety having 1-4 carbon atoms, a dialkylamino group or a saturated monocyclic heterocyclic ring selected from the group consisting of pyrrolidino, piperidino, morpholino or N-alkylpiperizino, or pharmaceutically acceptable acid addition salts thereof, wherein the alkyl moiety has 1-4 carbon atoms;

m is an integer from 1 to 5; and

n is an integer from 1 to 3.

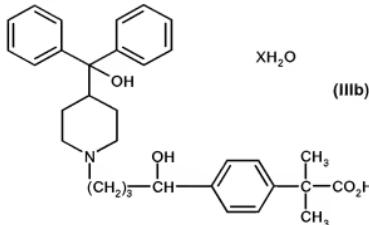
Claim 5 (Original): The composition according to Claim 4, wherein the piperidinoalkanol compound is 4-[4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]-α,α-dimethylbenzeneacetic acid hydrochloride.

Claim 6 (Original): The composition according to Claim 5, wherein the piperidinoalkanol compound has Formula (IIIa) as follows:



wherein X is a number from about 0 to about 5.

Claim 7 (Original): The composition according to Claim 5, wherein the piperidinoalkanol compound has Formula (IIIb) as follows:



wherein X is a number from about 0 to about 5.

Claim 8 (Original): The composition according to Claim 1, wherein the filler in Formulation (A) is selected from the group consisting of lactose, sucrose, dextrose, starch, pre-gelatinized starch, mannitol, sorbitol, xylitol, microcrystalline cellulose, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate and mixtures thereof.

Claim 9 (Cancelled).

Claim 10 (Original): The composition according to Claim 1, wherein the lubricant in Formulation (A) is selected from the group consisting of hydrogenated vegetable oil, hydrogenated castor oil, polyethylene glycol, stearic acid, calcium stearate, magnesium stearate, sodium stearate, sodium stearyl fumarate, and mixtures thereof.

Claim 11 (Cancelled).

Claim 12 (Original): The composition according to Claim 1, wherein the sugar in Formulation (B) is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, maltose, fructose, and mixtures thereof.

Claim 13 (Original): The composition according to Claim 1, wherein the disintegrant in Formulation (B) is selected from the group consisting of starch, sodium starch glycolate, pre-gelatinized starch, low substituted hydroxypropyl cellulose, croscarmellose sodium, cross-linked polyvinylpyrrolidone, microcrystalline cellulose, and mixtures thereof.

Claim 14 (Original): The composition according to Claim 1, wherein the disintegrant is a low-substituted hydroxypropyl cellulose.

Claim 15 (Original): The composition according to Claim 14, wherein the low-substituted hydroxypropyl cellulose is selected from the group consisting of: LH-11 having a hydroxypropoxy content of 11% and an average particle size of 50 microns; LH-21 having a hydroxypropoxy content of 11% and an average particle size of 40 microns; LH-31 having a hydroxypropoxy content of 11%, and an average particle size of 25 microns; LH-22 having a hydroxypropoxy content of 8%, and an average particle size of 40 microns; LH-32 having a hydroxypropoxy content of 8%, and an average particle size of 25 microns; LH-20 having a hydroxypropoxy content of 13%, and an average particle size of 40 microns; and LH-30 having a hydroxypropoxy content of 13%, and an average particle size of 25 microns.

Claim 16 (Original): The composition according to Claim 1, wherein the lubricant in Formulation (B) is selected from the group consisting of hydrogenated vegetable oil, hydrogenated castor oil, polyethylene glycol, stearic acid, calcium stearate, magnesium stearate, sodium stearate, sodium stearyl fumarate, and mixtures thereof.

Claim 17 (Cancelled).

Claim 18 (Currently Amended): A pharmaceutical composition in the form of a bilayer tablet comprising:

(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) from about 1 wt. % to about 30 wt. % of a filler; (ii) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least 80,000; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [2] 10 wt. % to about [[50]] 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof; and (v) from about 0.1 wt. % to about 3 wt. % of a lubricant, wherein the weight percents in the first discrete portion are based on the total weight of Formulation (A); and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second

carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' from about 10 wt. % to about 70 wt. % of a sugar; (ii)' from about 1 wt. % to about 40 wt. % of a disintegrant; and (iii)' from about 0.1 wt. % to about 3 wt. % of a lubricant, wherein the weight percents in the second discrete portion are based on the total weight of Formulation (B).

Claim 19 (Original): The composition according to Claim 18, wherein the filler in Formulation (A) is present in an amount from about 5 wt. % to about 20 wt. %.

Claim 20 (Original): The composition according to Claim 1, wherein the cellulose binder in Formulation (A) is present in an amount from about 20 wt. % to about 50 wt. %.

Claim 21 (Original): The composition according to Claim 1, wherein the ethylcellulose in Formulation (A) is present in an amount from about 10 wt. % to about 35 wt. %.

Claim 22 (Original): The composition according to Claim 1, wherein the wax in Formulation (A) is present in an amount from about 10 wt. % to about 30 wt. %.

Claim 23 (Original): The composition according to Claim 1, wherein the lubricant in Formulation (A) is present in an amount from about 0.5 wt. % to about 2 wt. %.

Claim 24 (Original): The composition according to Claim 1, wherein the sugar in Formulation (B) is present in an amount from about 25 wt. % to about 65 wt. %.

Claim 25 (Original): The composition according to Claim 1, wherein the disintegrant in Formulation (B) is present in an amount of from about 5 wt. % to about 25 wt. %.

Claim 26 (Original): The composition according to Claim 1, wherein the lubricant in Formulation (B) is present in an amount from about 0.5 wt. % to about 2 wt. %.

Claim 27 (Currently Amended): A pharmaceutical composition comprising a bilayer tablet which comprises:

(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) a filler; (ii) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [[2]] 10 wt. % to

about [[50]] 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof; and (v) a lubricant; and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' a sugar; (ii)' a disintegrant; and (iii)' a lubricant

wherein the composition is essentially free of a glidant.

Claim 28 (Original): The composition according to Claim 1, wherein the bilayer tablet is coated.

Claim 29 (Original): The composition according to Claim 1, wherein the piperidinoalkanol compound is fexofenadine hydrochloride which is present in an amount of about 60 mg and the sympathomimetic drug is pseudoephedrine hydrochloride which is present in an amount of about 120 mg.

Claim 30 (Currently Amended): A pharmaceutical composition comprising a bilayer tablet which comprises:

(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) lactose monohydrate; (ii) from about 10 wt. % to about 60 wt. % of hydroxypropyl methylcellulose; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [[2]] 10 wt. % to about [[50]] 30 wt. % of stearyl alcohol; and (v) magnesium stearate; and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' a sugar; (ii)' a disintegrant; and (iii)' a lubricant.

Claim 31 (Currently Amended): A pharmaceutical composition comprising a bilayer tablet which comprises:

(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) a filler; (ii) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [[2]] 10 wt. % to about [[50]] 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof; and (v) a lubricant; and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' lactose; (ii)' low-substituted hydroxypropyl cellulose; and (iii)' magnesium stearate.

Claim 32 (Currently Amended): A pharmaceutical composition comprising a bilayer tablet which comprises:

(a) a first discrete portion of the tablet Formulation (A) which comprises a sympathomimetic drug, or a pharmaceutically acceptable salt thereof, and a first carrier base material which provides a sustained-release of the sympathomimetic drug or the pharmaceutically acceptable salt thereof, said first carrier base material comprising a mixture of: (i) lactose monohydrate; (ii) from about 10 wt. % to about 60 wt. % of hydroxypropyl methylcellulose; (iii) from about 5 wt. % to about 50 wt. % of ethylcellulose; (iv) from about [[2]] 10 wt. % to about [[50]] 30 wt. % of stearyl alcohol; and (v) magnesium stearate; and

(b) a second discrete portion of the tablet Formulation (B) which comprises a piperidinoalkanol compound, or a pharmaceutically acceptable salt thereof, and a second carrier base material which provides an immediate-release of the piperidinoalkanol or the pharmaceutically acceptable salt thereof, said second carrier base comprising a mixture of: (i)' lactose; (ii)' low-substituted hydroxypropyl cellulose; and (iii)' magnesium stearate.